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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,914	09/30/2003	Bevil J. Hogg	5236-000452	8982

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ST. LOUIS, MO 63105

EXAMINER
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ROGERS, KRISTIN D

ART UNIT	PAPER NUMBER
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3736

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/674,914	<b>Applicant(s)</b> HOGG ET AL.	
	<b>Examiner</b> Kristin D. Rogers	<b>Art Unit</b> 3736	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 October 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) 7,18-22,26,31-32,36-37 and 41-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-17,23-25,27-30,33-35,38-40 and 49-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments with respect to claims 1-6, 8-17, 23-25, 27-30, 33-35, and 38-40 have been considered but are moot in view of the new ground(s) of rejection. The Examiner acknowledges the addition of new claims 49-53 and cancellation of claims 41-48.

### ***Claim Objections***

2. Claim 53 is objected to because of the following informalities: It appears that claim 53 lacks completeness and the subject matter that the Applicant is claiming is indefinite. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-6, 8-17, 33-35, 38-40, 49-50, and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Burnside et al. (6237604). In regard to claims 1, 33 and 38, Burnside et al. shows a medical navigation system for controlling the distal end of

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an elongate flexible medical device in a subject's body (Figure 1), the system comprising: an elongate flexible medical device 22, together with an electronic identification device for elongate flexible medical device identification 12 and 50; a navigation device for actuating the distal end of an elongate flexible medical device and thereby changing its orientation 26 column 4 lines 54-63; an electronic interface for selectively operating the navigation device for selectively controlling the orientation of the distal end of the elongate flexible medical device 51, the electronic interface comprising a processor 68 and at least one software program that enables navigation control only in the presence of the electronic identification device, wherein the interface provides actuation instructions (column 2 line 35 to column 3 line 53). Burnside further shows that the electronic identification device includes information on the physical properties/characteristics of the elongate medical device (column 2, lines 21-24). In regard to claims 2, 35 and 38, the electronic identification device includes a memory, and wherein the interface includes a reader for reading the memory 50 (column 5 line 67 to column 6 line 2). In regard to claim 3, the electronic identification device includes a memory unit and a processing unit that communicates with the interface for transferring information (column 7 lines 6-38). In regard to claims 4 and 5, the memory contains unique identifying information about the type of device, and wherein the interface includes a database of the unique identifying information of the type of devices with which the interface is intended to operate (column 12 line 44 to column 13 line 59). In regard to claim 6, the electronic identification device is a circuit that is connected to the interface 12 and 50 (figures 1, 2, 7, 10, and 12). In regard to claims 8-9 and 40-41,

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the memory contains unique identifying information about the device, and wherein the interface includes a database of the unique identifying information for devices with which the interface is intended to operate (column 2 lines 15-29). In regard to claim 10, the electronic identification device is a RF circuit that transmits a signal to the interface 12. In regard to claim 11, the interface includes a plurality of programs, each adapted for use with a different type of elongate flexible medical device, each program operating only when an electronic identification device for the particular type of elongate flexible medical device is present (column 2 line 30 to column 3 line 34). In regard to claim 13, the interface operates on the electronic identification device to prevent reuse of the elongate flexible medical device (abstract). In regard to claim 14, the interface tracks elapsed time of use of the identified elongate flexible medical device and invalidates use of the identified elongate flexible medical device when the elapsed time exceeds a pre-defined limit (column 2 line 52 to column 3 line 35). In regard to claim 15, the processing unit operates on the memory unit to prevent reuse of the elongate flexible medical device (column 2 line 52 to column 3 line 35). In regard to claim 16, the electronic identification device includes memory, and wherein the interface adds to or deletes information stored on the memory to prevent reuse of the device (column 3 lines 9-35). In regard to claims 17, 34 and 39, wherein the at least one software program controls navigation by employing a computational model of flexible device physics. It is obvious that the device of Burnside et al. includes a processor and control circuitry, it is inherent that there is a program involved because it is the processor that tells a program what to do (column 3 lines 9-26 and also see Viswanathan 20040068173). In regard to

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claims 49-50, Burnside shows that the electronic identification device memory includes information on the physical properties/characteristics of the elongate medical device used in navigational control for guiding the device (column 2, lines 21-24). In regard to claim 53, a complete search and application of prior art has been made impossible due to the incompleteness/indefiniteness of the subject matter of claim 53.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 23 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burnside. In regard to claims 23 and 28, drafting a claim in Jepson format (i.e., the format described in 37 CFR 1.75(e); see MPEP § 608.01(m)) is taken as an implied admission that the subject matter of the preamble is the prior art work of another. In re Fout, 675 F.2d 297, 301, 213 USPQ 532, 534 (CCPA 1982). Burnside et al. shows a medical navigation system for controlling the distal end of an elongate flexible medical device in a subject's body (Figure 1), the system comprising: an elongate flexible medical device 22, together with an electronic identification device for elongate flexible medical device identification 12 and 50; a navigation device for actuating the distal end of an elongate flexible medical device and thereby changing its orientation 26 column 4 lines 54-63; an electronic interface for selectively operating the navigation device for selectively controlling the orientation of the distal end of the elongate flexible medical device 51, the electronic interface comprising a processor 68 and at least one software program that enables navigation control only in the presence of the electronic identification device, wherein the interface provides actuation instructions (column 2 line 35 to column 3 line 53). Burnside further shows that the electronic identification device includes information on the physical properties/characteristics of the elongate medical device (column 2, lines 21-24).

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9. Claims 24-25, 27, 29-30, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burnside in view of Osadchy (6266551). Burnside shows a medical navigation system for navigating the distal end of an elongate flexible medical device including a software program and memory, but is silent regarding the software program controlling the navigation by flexible device physics and a magnetic navigation system. Osadchy et al teaches a medical navigation system for navigating the distal end of an elongate flexible medical device inside a subject's body, the system comprising an elongate flexible medical device 20; a navigation device for actuating and orienting the distal end of the elongate medical device (column 7 lines 9-28 and column 9 lines 26-45); an interface comprising a processor and at least one software program for selectively controlling the navigation device to selectively orient the distal end of the elongate medical device 90, the improvement comprising an electronic identification device 90 provided with the elongate flexible medical device 20, which enables at least one navigation control software program of the interface to function. In regard to claims 24 and 29, at least one software program controls navigation by employing a computational model of flexible device physics 34. In regard to claims 25 and 30, the electronic identification device includes a memory, and wherein the interface is adapted to read the memory 90 (abstract). In regard to claim 27, Osadchy et al. teaches the electronic identification device is an integrated circuit including a memory 90 connected to the interface. In regard to claim 52, Osadchy et al. teaches a control system that is an electromagnetic navigation system for controlling the elongate medical device. Therefore it would have been obvious to one of ordinary skill in the art at the time of the



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invention to modify Burnside with a software program employing a computational model of flexible device physics and a magnetic navigation system as taught by Osadchy et al. since such modification would provide a more efficient steering system for the distal end of the elongate medical device.

10. Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burnside in view of Osadchy et al. as applied to claim 50 above, and further in view of Lee et al. (6714809). Burnside shows a medical navigation system for controlling the distal end of an elongate flexible medical device in a subject's body and an electronic identification device including information on the physical properties/characteristics of the elongate medical device (column 2, lines 21-24). Burnside is silent regarding the type of information that is characteristic of the physical and geometric properties of the device. Lee et al. teaches a steerable guidewire for navigation in the body comprising a connector serving as the identification means and an elongate medical device (guidewire). The identification system includes information pertaining to size (length or cross-sectional area). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Burnside with identification means for providing information regarding physical and geometric properties of the elongate medical device as taught by Lee et al. since such modification would provide a means to ensure that a desired medical device was used only once.

***Conclusion***

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristin D. Rogers whose telephone number is 571.272.7293. The examiner can normally be reached on Monday through Friday 8:00am - 4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571.272.4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
KDR

  
